

**Presentations and Publications of the Tuberculosis Trials Consortium**  
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**I. Publications**

**1999**

Vernon A, Burman W, Benator D, Khan A, Bozeman L for the Tuberculosis Trials Consortium. Acquired rifamycin mono-resistance among patients with HIV-related tuberculosis treated with supervised once weekly rifapentine and isoniazid. Lancet 1999; 353:1843-47.

**2001**

TB Trials Consortium. The Tuberculosis Trials Consortium: A Model for Clinical Trials Collaborations. Public Health Reports 2001; 116 (Supplement 1):41-49.

**2002**

Centers for Disease Control & Prevention. Notice to Readers: Acquired Rifamycin Resistance in Persons with Advanced HIV Disease Being Treated for Active Tuberculosis with Intermittent Rifamycin-Based Regimens. Morb Mort Wkly Rep 2002; 51:214-5.

N Bock, T Sterling, CD Hamilton, C Pachucki, YC Wang, DS Conwell, A Mosher, M Samuels, and A Vernon for the TBTC. A prospective, randomized, double-blind study of the tolerability of rifapentine 600 mg, 900 mg and 1200 mg plus isoniazid in the continuation phase of tuberculosis treatment. Amer J Resp Crit Care Med 2002; 165: 1526-1530.

TB Trials Consortium. Once-weekly rifapentine and isoniazid versus twice-weekly rifampin and isoniazid in the continuation phase of therapy for drug-susceptible pulmonary tuberculosis: a prospective, randomized clinical trial. Lancet 2002; 360:528-34.

**2003**

Weiner M, Burman W, Vernon A, Benator D, Peloquin CA, Khan A, Weis S, King B, Shah N, Hodges T, TBTC. Low isoniazid concentrations and outcome of tuberculosis treatment with once-weekly isoniazid and rifapentine. Am J Respir Crit Care Med 2003; 167:1341-7.

Burman W, Breese P, Weis S, Bock N, Bernardo J, Vernon A, TBTC. The effects of local review on informed consent documents from a multicenter clinical trials consortium. Clinical Trials 2003;24:245-55.

**II. Presentations and Abstracts**

**1997**

Bozeman L, Vernon A, Crawford J, Glickman S, Dansbury K, Villarino E and the USPHS Rifapentine Trials Group. Drug susceptibility testing (DST) of M. tuberculosis (M.TB) isolates from patients enrolled in a clinical trial. [abstract]. Am J Respir Crit Care Med 1997;155:A220.

Rifapentine Trial Group: Design of USPHS Study 22: A trial of once weekly isoniazid and rifapentine in the continuation phase of TB treatment.[abstract] Am J Respir Crit Care Med 1997;155:A255.

Vernon A, Villarino E, O'Brien R et al. Relapse with rifampin mono-resistant TB (RMR-TB) in HIV-positive TB patients treated with a once weekly rifapentine-containing regimen [abstract]. Int J Tuberc Lung Dis 1997;1

Suppl.A:S51-2.

#### 1998

Benator D, Burman W, Chaisson R, and USPHS Study 22 Investigators. Acquired rifamycin monoresistant tuberculosis among HIV-infected patients treated with once-weekly isoniazid and rifapentine. 5<sup>th</sup> Conference on Retroviruses and Opportunistic Infections. Chicago, IL, February 1998.

Vernon A, Khan A, Bozeman L, et al. Update on US Public Health Service (USPHS) Study 22: A trial of once weekly isoniazid (INH) & rifapentine (RFP) in the continuation phase of TB treatment [abstract]. *Am J Respir Crit Care Med* 1998;157:A467.

Vernon A. TB Clinical Trials in the US. Oral presentation, evening symposium, American Thoracic Society International Conference, Chicago, IL, April 1998.

#### 1999

Burman W, Vernon A, Benator D for the TB Trials Consortium. Isoniazid, rifampin and rifapentine in human plasma: no need to add ascorbic acid to maintain stability. [abstract]. *Am J Respir Crit Care Med* 1999;159:A496.

Horsburgh CR, Reichman LB, Vernon A, Gordin F, Villarino ME, O'Brien R, for the TBTC Investigators. Establishment of the Tuberculosis Trials Consortium (TBTC). Invited presentation, 1999 American Thoracic Society International Conference, San Diego, CA.

Peloquin CA, Vernon A, Burman W, Benator D, for the TB Trials Consortium. Pharmacokinetics of rifapentine, rifampin, isoniazid in TB patients. [abstract]. *Am J Respir Crit Care Med* 1999;159:A416.

Bock N, for the Tuberculosis Trials Consortium. Safety and tolerability of once-weekly rifapentine/isoniazid (INH) vs. twice-weekly rifampin/INH in the continuation phase therapy of pulmonary tuberculosis in HIV-negative adults in USPHS Study 22. Poster presentation, 30<sup>th</sup> IUATLD World Conference on Lung Health, Madrid (Spain), September 1999.

#### 2000

A Vernon for the TB Trials Consortium. TBTC Study 22 (Rifapentine Trial): Preliminary Results in HIV-negative Patients. Invited presentation at Rifapentine Evening Symposium, Meeting of the European Region of the IUATLD, Budapest (Hungary), April 2000.

A Vernon for the TB Trials Consortium. TBTC Study 22 (Rifapentine Trial): Preliminary Results in HIV-negative Patients. [abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A252.

A Catanzaro, R Horsburgh for the TB Trials Consortium. TBTC Study 22: Risk Factors for Relapse with Once-weekly Isoniazid/rifapentine (HP) in HIV-negative TB Patients. [abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A252.

F.Gordin, R.Chaisson for the TB Trials Consortium. TBTC Study 22: Risk Factors for Relapse with Twice-weekly Isoniazid/rifampin (HR) in HIV-negative TB Patients. [abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A252.

Z. Taylor, Qualls N, Vernon A, Villarino E, O'Brien R. A prevention effectiveness study of rifapentine in the continuation phase of therapy for active pulmonary tuberculosis.[abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A524.

A. Khan, L. Sandman, A. Mosher, D. Pizzano for the TB Trials Consortium. TBTC Study 22 (Rifapentine Trial): Preliminary quality assurance results in HIV-negative Patients. [abstract]. *Am J Respir Crit Care Med* 2000; 161(suppl):A645.

Villarino ME, O'Brien RJ for the TB Trials Consortium. TBTC Study22: Rifapentine Clinical Trial. Results in HIV-negative patients with pulmonary tuberculosis. Presented at the Australian Society of Microbiology Conference on TB in the New Millenium, June 2000.

Catanzaro A, Villarino ME, for the TB Trials Consortium. Rate of and risk factors for relapse after once-weekly treatment with isoniazid and rifapentine for pulmonary tuberculosis. Presented at the Australian Society of Microbiology Conference on TB in the New Millenium, June 2000.

Reichman LB, Villarino ME, for the TB Trials Consortium. Evaluation of the standard short course therapy (SSCT) for treatment of pulmonary tuberculosis (TB): results from TBTC Study 22. Presented at the Australian Society of Microbiology Conference on TB in the New Millenium, June 2000.

Burman W, for the Tuberculosis Trials Consortium. Should tuberculosis treatment be extended in selected patients? Data from TBTC Study 22 and review of previous studies (poster). 38<sup>th</sup> Annual IDSA Meeting, New Orleans LA, Sept 7-10, 2000

Chaisson RE, El-Sadr W, for the TB Trials Consortium. Weekly Rifapentine and INH versus Twice Weekly Rifampin/INH in the Continuation Phase of Therapy for HIV Negative Patients with Pulmonary Tuberculosis (TB): Final Results; USPHS Study 22 (poster). ICAAC, 2000.

## 2001

Carol Dukes Hamilton, William N. Rom, for the TB Trials Consortium. Clinical Correlates of Sub-optimal Response to Tuberculosis (TB) Therapy in Humans (abstract). Keystone Symposium, February 2001.

Weiner M, Khan A, Benator D, Peloquin C, Burman W, and the TB Trials Consortium. Low Isoniazid (INH) Levels Are Associated with TB Treatment Failure/Relapse with Once-Weekly Rifapentine (RPT) and INH [abstract]. *Am J Respir Crit Care Med* 2001; 163(suppl):A498.

Peloquin C, Benator D, Hayden K, Pizzano D, and the TB Trials Consortium. Low Rifapentine, Rifampin, & Isoniazid Plasma Levels Are Not Predicted by Clinical And Demographic Features [abstract]. *Am J Respir Crit Care Med* 2001; 163(suppl):A498.

A. Vernon, D. Benator, N. Shah, T. Hodge and the TB Trials Consortium. N-Acetyl transferase type 2 Genotype Correlates with Treatment Failure or Relapse of Intermittent Isoniazid-containing Short-course Therapy [abstract]. *Am J Respir Crit Care Med* 2001; 163(suppl):A498.

N. Bock, Sterling T, Pachucki C, Conwell D, Wang YC, for the TB Trials Consortium. Tolerability of Once-weekly Rifapentine 900 mg plus INH vs Once-weekly Rifapentine 600 mg plus INH during Continuation Phase Treatment of Pan-susceptible Tuberculosis in HIV-negative Adults [abstract]. *Am J Respir Crit Care Med* 2001; 163(suppl):A497. (poster).

Weiner M, Vernon A, Benator D, Khan A, Peloquin C, Hodge T and Burman W, for the TB Trials Consortium. Low Isoniazid Levels Are Associated with Tuberculosis Treatment Failure or Relapse with Once-Weekly, Short

Course Rifapentine and Isoniazid [abstract]. *Int Journal TB and Lung Disease* 2001;5 (Supp 1):S120. Poster presented at 32<sup>nd</sup> World Conference of the International Union Against Tuberculosis and Lung Disease, Paris FRANCE, November 2001.

Burman W, Breese P, Weis S, Bock N, Bernardo J, Vernon A, for the TB Trials Consortium. The effects of local review on informed consent documents from a multicenter clinical trials consortium. Poster presented at the 15<sup>th</sup> Annual Applied Research Ethics National Association (ARENA) Meeting, Boston MA, December 2001.

## 2002

L Sandman, a Khan, A Mosher, J Tapy, A Vernon, and the TB Trials Consortium. Data Quality Assurance in the Tuberculosis Trials Consortium: A Partnership Approach. Submitted to 2002 Society for Clinical Trials conference, Arlington VA. *Controlled Clinical Trials* 2002; 23:63S (poster).

D Conwell, A Khan, J Tapy, L Sandman, A Mosher, S Barnes, M Bhattacharya, A Vernon, and the TB Trials Consortium (TBTC). Preventable Loss to Follow-Up (F/U) in a Large TB Treatment Trial (TBTC Study 22). Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A293. (poster).

A Khan, R Reves, T Sterling, A Vernon, S Weis, and the TB Trials Consortium (TBTC). Weight, Body Mass Index, and Treatment Outcome in a Large TB Treatment Trial (TBTC Study 22). Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A293. (poster).

L Bozeman, R Chaisson, G Dickinson, B Mangura, N Schluger, T Sterling, A. Vernon, Y-C Wang, and the TB Trials Consortium. Mortality in a Large TB Treatment Trial. Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A713 (poster).

L Bozeman, W Burman, F Gordin, B Metchock, C Peloquin, M. Weiner, and the TB Trials Consortium (TBTC). Fluoroquinolone Susceptibility Among Mycobacterium tuberculosis Isolates from the United States and Canada. Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A18 (oral presentation).

M Bhattacharya, L Bozeman, W Burman, D Cave, B Metchock, J Tapy, A Vernon, C Woodley, and the TB Trials Consortium (TBTC). Usefulness of DNA fingerprinting of Mycobacterium tuberculosis in a large clinical trial of tuberculosis treatment. Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A713 (poster).

CA Peloquin, N Bock, M Weiner, A Vernon and TB Trials Consortium (TBTC). Pharmacokinetics of Rifapentine Used at High Doses in Patients with TB Disease. Submitted to American Thoracic Society 2002 International Conference [abstract]. *Am J Respir Crit Care Med* 2002; 165 (suppl):A713 (poster).

A Vernon, CR Horsburgh, B Burman, and the TB Trials Consortium. TBTC Study 22/Once-Weekly Isoniazid/Rifapentine (HP1) Vs Twice-Weekly Isoniazid/Rifampin (HR2) In HIV-Negative TB Patients. – In Whom Can Once-Weekly Therapy Be Safely Used? [abstract 146]. Program and Abstracts of the 4<sup>th</sup> World Congress on Tuberculosis, Bethesda MD, June 2002; 86.

Benator D, Burman W, Vernon A, Weiner M, Villarino E, Jones B, Silva C, Weis S, Lahart C, King B, Mangura B, Weiner M, El-Sadr W and the TB Trials Consortium (TBTC). Acquired Rifamycin Resistance is Associated with Intermittent Treatment of Tuberculosis in Patients with Advanced HIV infection: Preliminary Results of TBTC Study 23 and review of previous studies [abstract]. Program and Abstracts of the 4<sup>th</sup> World Congress on Tuberculosis, Bethesda MD, June 2002; 12-13.

A Vernon, A Khan, B Burman, CR Horsburgh, and the TB Trials Consortium. TBTC Study 22: Risk Factors For Failure/Relapse With Once-Weekly Isoniazid/Rifapentine (Hp) Or Twice-Weekly Isoniazid/Rifampin (Hr) In Sputum Smear-Positive Hiv-Negative Tb Patients – An Analysis For Resource-Poor Settings. Poster presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis*

2002;6(Suppl 1):S124.

W. Burman, D Benator, W Burman, A Vernon, M Weiner, E Villarino B Jones, C Silva, S Weis, C Lahart, B King, B Mangura, W El-Sadr and the Tuberculosis Trials Consortium (TBTC). Acquired Rifamycin Resistance Is Associated With Intermittent Treatment Of Tuberculosis In Patients With Advanced Hiv Infection: Preliminary Results Of TBTC Study 23. Oral presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis* 2002;6(Suppl 1):S149-50.

M Weiner, A Khan, A Vernon, B Burman, B Jones for the Tuberculosis Trials Consortium. Epidemiologic and clinical factors associated with the endpoint of *M. tuberculosis* culture-positivity in sputa after two-months of therapy for pulmonary tuberculosis. Poster presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis* 2002;6(Suppl 1):S189.

CA Peloquin, N Bock, M Weiner, A Vernon and the TB Trials Consortium (TBTC). Pharmacokinetics of Rifapentine Used at High Doses in Patients with TB Disease. Poster presentation, IUATLD World Conference on Lung Health, Montreal CANADA, October 2002. *Int J Tuberc Lung Dis* 2002;6(Suppl 1):S128-9.

## 2003

Burman W, Welch L, Metchock B, Bozeman L, Weiner M and the Tuberculosis Trials Consortium. The frequency and genetic basis of fluoroquinolone resistance among *Mycobacterium tuberculosis* isolates [abstract]. In: Tuberculosis: integrating host and pathogen biology. Jan 25-30, 2003, Santa Fe. Keystone Symposium, page 100.

Burman W, Benator D, Vernon A, Khan A, El-Sadr W, Silva C, Lahart C, Mangura B, King B, Weiner M, Jones B and the TB Trials Consortium. Use of antiretroviral therapy during treatment of active TB with a rifabutin-based regimen: TBTC Study 23 [abstract 136]. Abstracts of the 10th Conference on Retroviruses and Opportunistic Infections, Boston MA, February 2003;106. (Oral Presentation)

Benator D, Peloquin C, Vernon A, Khan A, Jones B, Weis S, Weiner M, Burman B, TBTC. Low serum levels of isoniazid are associated with acquired rifamycin resistance among patients with HIV-related TB treated with largely twice-weekly rifabutin and isoniazid [abstract]. *Am J Respir Crit Care Med* 2003;167:A433.

Bock NN, Sterling TR, Khan A, Hamilton C, Pachucki C, Mosher A, Samuel M, Conwell D, Vernon AA, TBTC. Extension of continuation-phase therapy to reduce relapse rates among HIV-negative TB patients at thigh risk for relapse [abstract]. *Am J Respir Crit Care Med* 2003;167:A433.

Weiner M, Bock N, Peloquin CA, Burman WJ, Khan A, Vernon A, Zhao Z, Weis S, Sterling T, Hayden K, Goldberg S, Tuberculosis Trials Consortium. Rifapentine Pharmacokinetics with 600, 900 or 1,200 mg Doses in Patients with Tuberculosis during Once-Weekly Continuation-Phase Therapy. 34th IUATLD World Conference on Lung Health, Paris, Oct 29 (in press).

## III. Manuscripts and Presentations/Abstracts submitted or in preparation

### A. Manuscripts in preparation

Conwell D, Mosher A, Khan A, Tapy J, Sandman L, Battacharaya M, Vernon A, Horsburgh CR and the TB Trials Consortium (TBTC). Risk factors for loss to follow-up in a large tuberculosis treatment trial.

A Khan, R Reves, T Sterling, A Vernon, S Weis and the TB Trials Consortium (TBTC). Weight, Body Mass Index, and Treatment Outcome in a Large Tuberculosis Treatment Trial (TBTC Study 22).

Weiner M, Bock N, Peloquin CA, Burman WJ, Khan A, Vernon A, Zhao Z, Weis S, Sterling T, Hayden K, Goldberg S and the Tuberculosis Trials Consortium (TBTC). Rifapentine Pharmacokinetics with 600, 900 or 1,200 mg Doses in Patients with Tuberculosis during Once-Weekly Continuation-Phase Therapy.

Sterling T, Bozeman L, Mangura B, Schluger N, Vernon A, and the TB Trials Consortium. Mortality in a Large TB Treatment Trial.

L Bozeman, W Burman, F Gordin, B Metchock, C Peloquin, M. Weiner, and the TB Trials Consortium (TBTC). Fluoroquinolone Susceptibility Among *Mycobacterium tuberculosis* Isolates from the United States and Canada.

Jasmer R, Saukkonen J, Schwartzman K, L Bozeman, Burman W, D Cave, B Metchock, J Tapy, A Vernon, C Woodley, and the TB Trials Consortium (TBTC). Usefulness of DNA fingerprinting of *Mycobacterium tuberculosis* in a large clinical trial of tuberculosis treatment.

Burman W, Benator D, Vernon A, Khan A, Jones B, Silva C, Lahart C, Weis SE, King B, Mangura B, Weiner M, El-Sadr W, TBTC. Treatment of HIV-related tuberculosis with largely twice-weekly rifabutin plus isoniazid. (submitted)

Sandman L, Khan A, Mosher A, Tapy A, Condos R, Ferrell S, Vernon A, TBTC. Development and Implementation of a Quality Assurance Program in a Large Clinical Trials Consortium: Experience of the Tuberculosis Trials Consortium.

Bock N, et al. Study 25 follow-up manuscript.

#### **B. Presentations and Abstracts submitted or in preparation**

Weiner M, Burman B, Khan A, Peloquin C, Benator D, Vernon A, Zhao Z, Weis S and Tuberculosis Trials Consortium (TBTC). The Effect of HIV Serostatus on Isoniazid Pharmacokinetics Among Patients with Active Tuberculosis. (submitted for ATS 2004).

Benator DA, Weiner M, Burman WJ, Vernon A, Zhao Z, Khan A, Sandman L, Engle M, Silva C, Peloquin CA, Hsyu P, Becker M and the Tuberculosis Trials Consortium (TBTC). Intensive Pharmacokinetics of the Nelfinavir – Rifabutin Interaction in Patients with HIV Related Tuberculosis Treated with a Twice-Weekly Rifabutin-Based Regimen. (submitted for ATS 2004)

Weiner M, Peloquin C, Khan A, Vernon A, Engle M, Benator D, Fitzgerald M, Zhao Z, Burman W and the Tuberculosis Trials Consortium (TBTC). Intermittent Rifabutin and Isoniazid with Daily Efavirenz in Combination with Two Nucleosides for Treatment of HIV Infection and Tuberculosis Disease. (accepted for presentation at CROI in 2004)